Notice of Allowability	Application No.	Applicant(s)	
	10/748,185	HALOW, GEORGE M.	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Telephonic Interview on 3/30/07 and Amendment filed 01/22/07*.

2. ☒ The allowed claim(s) is/are *6-9,16,33-36,38-41 and 53-63*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20070330* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

BRIAN-YONG S. KWON
PRIMARY EXAMINER

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jean A. Buttmi on 03/30/07.

Supports for applicant's amendments "orally", "free of serum electrolytes" and "from about 0.15 to 3.5 parts by weight polyethylene glycol (PEG) and to about 1 part by weight of lactulose" in claim 33 are found in the original claims 34 and 23 and page 6, lines 12-13 respectively. Furthermore, supports for applicant's amendments "about 10 to 20 gm PEG and about 10 to 20 gm lactulose" and "dissolved in the aqueous carrier" in claim 9 are found in page 6, lines 12-13 and 24-25 respectively.

The application has been amended as follows:

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What Is Claimed is:

1. (Cancelled)
2. (Cancelled)
3. (Cancelled)
4. (Cancelled)
5. (Cancelled)

6. (Previously Presented) The method of claim 33, wherein the composition comprises from about 0.5 to 3 parts by weight PEG to 1 part by weight lactulose.

7. (Previously Presented) The method of claim 34, wherein the composition is administered in single dosages each comprising about 5 to 35 gm of dry PEG dissolved in the aqueous carrier.

8. (Previously Presented) The method of claim 7, wherein each single dosage further comprises about 10 to 30 gm of dry lactulose dissolved in the aqueous carrier.

9. (Currently Amended) The method of claim 8, wherein each single dosage comprises about 10 to 20 gm PEG and about 10 to 20 gm lactulose dissolved in the aqueous carrier.

10. (Cancelled)
11. (Cancelled)
12. (Cancelled)
13. (Cancelled)
14. (Cancelled)
15. (Cancelled)

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16. (Previously Presented) The method of claim 33, wherein the PEG is solid at room temperature.

17. (Cancelled)
18. (Cancelled)
19. (Cancelled)
20. (Cancelled)
21. (Cancelled)
22. (Cancelled)
23. (Cancelled)
24. (Cancelled)
25. (Cancelled)
26. (Cancelled)
27. (Cancelled)
28. (Cancelled)
29. (Cancelled)
30. (Cancelled)
31. (Cancelled)
32. (Cancelled)

33. (Currently Amended) A method for the treatment of a patient with ~~or at risk of~~ hyperammonemia, comprising orally administering to the patient a pharmaceutical composition free of serum electrolytes and comprising from about 0.15 to 3.5 parts by weight polyethylene glycol (PEG) ~~and~~ to about 1 part by weight lactulose, in an amount and frequency sufficient to reduce patient plasma ammonia to a clinically-acceptable level or to maintain this level, or both.

34. (Currently Amended) The method of claim 33, wherein the composition is a dry composition formulated as a liquid drink

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by admixture with a pharmaceutically-acceptable aqueous carrier ~~and is orally administered to the patient~~.

35. (Previously Presented) The method of claim 7, wherein the composition is administered on a continuing basis in at least one single dosage per day.

36. (Previously Presented) The method of claim 8, wherein the composition is administered on a continuing basis in at least one single dosage per day.

37. (Cancelled)

38. (Currently Amended) The method of claim 9, wherein the composition is administered on a continuing basis in at least a one single ~~dose~~ dosage per day.

39. (Previously Presented) The method of claim 35, wherein the composition is administered on a continuing basis of once or twice a day.

40. (Previously Presented) The method of claim 36, wherein the composition is administered on a continuing basis of once or twice a day.

41. (Previously Presented) The method of claim 38, wherein the composition is administered on a continuing basis of once or twice a day.

42. (Cancelled)

43. (Cancelled)

44-52. (cancelled)

53. (New) The method of claim 6, wherein the composition is a dry composition formulated as a liquid drink by admixture with a pharmaceutically-acceptable aqueous carrier.

54. (New) The method of claim 53, wherein the composition is administered in single dosages each comprising about 5 to 35 gm of dry PEG dissolved in the aqueous carrier.

55. (New) The method of claim 54, wherein each single dosage further comprises about 10 to 30gm of dry lactulose dissolved in the aqueous carrier.

56. (New) The method of claim 55, wherein each single dosage comprises about 10 to 20 gm PEG and about 10 to 20 gm lactulose.

57. (New) The method of claim 54, wherein the composition is administered on a continuing basis in at least one single dosage per day.

58. (New) The method of claim 55, wherein the composition is administered on a continuing basis in at least one single dosage per day.

59. (New) The method of claim 56, wherein the composition is administered on a continuing basis in at least one single dosage per day.

60. (New) The method of claim 57, wherein the composition is administered on a continuing basis of once or twice a day.

61. (New) The method of claim 58, wherein the composition is administered on a continuing basis of once or twice a day.

62. (New) The method of claim 59, wherein the composition is administered on a continuing basis of once or twice a day.

63. (New) The method of claim 6, wherein PEG is a solid at room temperature.

2. Claims 6-9, 16, 33-36, 38-41 and 53-63 are allowed.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon
Primary Patent Examiner
AU 1614